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ORIGINAL

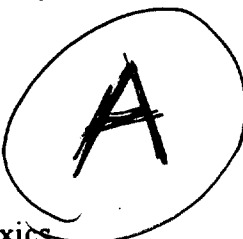
ciba

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March 2, 1995

Document Processing Center (7407)  
(Attn.: Section 8(e) Coordinator)  
Office of Pollution Prevention and Toxics  
U. S. Environmental Protection Agency  
401 M Street, SW  
Washington, DC 20460



EXPRESS MAIL  
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Contains No CBI



RE.: TSCA Section 8(e) Notice; CAS No. 71566-26-2

Dear Section 8(e) Coordinator:

This letter and the enclosed study contain no Confidential Business Information.

In accordance with EPA's March 16, 1978, policy statement on Section 8(e) reporting under the Toxic Substances Control Act and EPA's June 1991 TSCA Section 8(e) Reporting Guide, Ciba wishes to bring to your attention acute toxicity observed in zebra-fish with CAS No. 71566-26-2. Chemically, CAS No. 71566-26-2 is Cobaltate(1-), bis[2-[(2-hydroxy-5-nitrophenyl)azo]-3-oxo-N-phenylbutanamidato(2-)]-, sodium. The product tested also contains 4% of the 4-nitrophenyl isomer, CAS No. 81361-02-6. CAS No. 71566-26-2 is an imported pigment that is sold commercially in the United States. It is used for organic solvent based ink products.

Acute toxicity was determined in zebra-fish in accordance with OECD Guideline 203 under static conditions. The test material, dissolved in tetrahydrofuran, was added to the aquaria at various concentrations and appeared to be homogeneously distributed. The 96-hour  $LC_{50}$  was calculated to be 0.057 mg/l, under these artificial conditions. A copy of the final report, entitled "Test for Acute Toxicity of TK 10011 to Zebra-Fish (*Brachydanio rerio*), (OECD-Guideline No. 203, Paris 1984)," is enclosed.

Although we do not have an experimentally determined value for the octanol/water partition coefficient for the substance in question, a recently obtained value, calculated by our parent company in Basel, Switzerland, showed the Log P to be 6.52 (Fragment method, C. Hansch and A. Leo, Computer program CLOP 3.4). In spite of this chemical substance's potential to bioaccumulate, as evidenced by the high calculated Log P, Ciba is not aware of any significant potential for widespread exposure. Ink makers routinely handle wastes of the subject chemical as hazardous wastes, which are subsequently incinerated. (Cobalt compounds are regulated under Section 313 of SARA Title III.) It is highly unlikely that even small quantities of this product would find its way into aqueous environments, since the

3-15-95

mixture would color the water intensely, and would alarm any POTW, or other waste stream operators. Additionally, the subject chemical is not water soluble.

Ciba is submitting this environmental effects information under TSCA Section 8(e) out of an excess of caution. We believe it may not be subject to 8(e) reporting, particularly if Part V(b)(2) and (3) of EPA's 1978 8(e) guidance are applied strictly. Under Part V(b)(2) of the guidance, reporting would be required if the following criteria are met: a) pronounced bioaccumulation as evidenced by an n-octanol water partition coefficient greater than 25,000 b) potential for widespread exposure, and c) any non-trivial adverse effect. Because "widespread" has not yet been defined by EPA, we do not know whether there is a potential for widespread exposure. Under Part V(b)(3), reporting would be required if the following criterion is met: any non-trivial adverse effect associated with a chemical known either a) to have bioaccumulated or b) to be widespread in environmental media. The subject chemical mixture is not known to have bioaccumulated and, as discussed above, the term "widespread" has not been defined by EPA.

As you know, EPA has suspended Part V(b)(1) of its 1978 guidance, which deals with widespread and previously unsuspected distribution in environmental media. We are concerned that the term, "widespread," may be subsequently defined in Part V(b) in such a manner as to require reporting of the information in this submission. We are therefore submitting the information now, and request EPA to inform us whether the information is, indeed, subject to immediate reporting under TSCA Section 8(e).

Ciba will include the acute zebra-fish toxicity finding on the Material Safety Data Sheet.

Please contact the undersigned if you need any additional information.

Very truly yours,



Anthony Di Battista

Project No.: 884049

CIBA-GEIGY Ltd.  
Basle, Switzerland  
GU 3 - Ecotoxicology

R E P O R T  
on the  
TEST FOR ACUTE TOXICITY  
of  
TK 10011

to Zebra-Fish (Brachydanio rerio)

(OECD-Guideline No. 203, Paris 1984)

RECEIVED  
04/08/88  
95NR-3 PM 2:52

Sponsor :  
Represented by :

CIBA-GEIGY Ltd., Basle / PA-Division  
Dr. A. von Schulthess / R-1002.2.54

Test substance :  
Generic/Trade name :  
Code No :  
Batch No. :

TK 10011  
ORASOL Gelb 3R  
TK 10011  
213415.79

Reported :

04/08/88

Study director :

... *Rufli* ..... 04/08/88 .....  
Dr. H. Rufli

Management :

... *de Morsier* ..... 08/08/88 .....  
Dr. A. de Morsier

Archives :

CIBA-GEIGY Ltd., Basle / R-1066.k.247

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1. S U M M A R Y

Study : Determination of LC 50 (96 h): Concentration at which 50% of the fish population died

Test substance : TK 10011

Test system : Zebra-Fish (*Brachydanio rerio*)

Duration : 96 hours

Temperature : 23 ± 1°C

Exposure : OECD-Guideline No. 203, Paris 1984 ,  
(static procedure)

Deviations : Highest vehicle concentration: 319 mg/l (see p. 6).

Results : LC 50 (96 h) calculated : 0.057 mg/l  
95% confidence limits : 0.047-0.069 mg/l

LC 50 (96 h) in test : 0.032 mg/l

LC 100 (96 h) in test : 0.10 mg/l

Remarks:

Values are based on nominal concentrations.

## 2. I N T R O D U C T I O N

Aim : At the request of the sponsor an acute toxicity study was conducted. This report describes the experimental techniques and the results obtained in this study determining the acute toxicity on fish of TK 10011

Exposure : OECD-Guideline No. 203, Paris 1984 (static procedure)

Deviations : Highest vehicle concentration: 319 mg/l (see p. 6).

Test begin : 18/07/88  
Test begin (exposure) : 18/07/88  
Test end (exposure) : 22/07/88

Remark : The test substance was identified on the basis of the code number. The characterisation and analysis were not part of the study and not within the responsibility of the study director.

## 3. P E R S O N N E L

Study Director : Dr. H. Rufli

Technical Personnel : S. Flury (technician)

The job descriptions and the summaries of training and professional experience for the personnel participating in this study are archived in the test facility.

4. M A T E R I A L S and M E T H O D S

<u>Test substance</u> :	TK 10011
Batch No. :	213415.79
Appearance :	powder
Purity :	commercial grade
Determined :	by the sponsor
Solubility in water :	insoluble in water
Received :	14/01/88
Storage :	room temperature
Stability :	guaranteed by the sponsor
Stock solution :	0.025 g TK 10011 were dissolved in and made up to 50 ml with tetrahydrofuran THF.
<u>Test system</u> :	Zebra-Fish ( <i>Brachydanio rerio</i> )
Number of fishes :	10 fishes per concentration and control 10 fishes per aquarium
Length :	21 mm (15-25 mm)
Weight :	0.11 g (0.02-0.20 g)
Loading :	0.07 g/l
Feeding :	None
Adaptation :	24 hours / no food 24 hours prior to exposure
Acclimatisation :	19 days
Treatment :	None
Supplier :	West Aquarium / D-3422 Bad Lauterberg

<u>Exposure</u> :	Glass aquaria of 20 liters filled with 15 liters (36/22/25 cm)
Water :	Dechlorinated tap water (carbon filter)
Hardness :	164 mg CaCO <sub>3</sub> /l
Temperature :	23 ± 1°C
Aeration :	none
Lighting :	Fluorescent light, 16 hours daily
Duration :	96 hours
Measurements :	oxygen, pH, temperature daily
<u>Test concentrations</u> (mg/l) :	0.010, 0.018, 0.032, 0.058, 0.10, 0.18
<u>Remarks (nominal)</u> :	Calculated amounts of test substance to produce the desired test concentrations were given into the water and were homogeneously distributed. The fish were then transferred into the aquaria.
Remarks :	The test substance appeared homogeneously distributed in all test concentrations.
Controls :	
Blank :	water
Vehicle :	319 mg tetrahydrofuran per liter water in the concentration used for the highest test concentration

## 5. C A L C U L A T I O N

The LC<sub>50</sub>-values were calculated according to SPEARMAN-KAERBER in: D.J. Finney, 524-530, London (1964).  
LC-values were graphically determined on gauss-logarithmic probability paper.



6. R E S U L T S

ACUTE TOXICITY of TK 10011

LC 50 (96h) calculated :	0.057	mg/l
95% confidence limits :	0.047-0.069	mg/l
LC 50 (72h) :	0.057	mg/l
95% confidence limits :	0.047-0.069	mg/l
LC 50 (48h) :	0.061	mg/l
95% confidence limits :	0.050-0.073	mg/l
LC 50 (24h) :	0.096	mg/l
95% confidence limits :	0.079-0.11	mg/l
LC 50 (96h) graphically determined :	0.058	mg/l
LC 0 (96h) in test :	0.032	mg/l
LC 100 (96h) in test :	0.10	mg/l
Controls :	Mortalities in blank :	0 %
	Mortalities in vehicle :	0 %

Remarks:

Values are based on nominal concentrations.

## 7. MEASUREMENTS / OBSERVATIONS

Table 1: Mortalities

Concentration nominal mg/l	Mortalities Number of dead fishes			
	24h	48h	72h	96h
Blank	0	0	0	0
Vehicle	0	0	0	0
0.01	0	0	0	0
0.018	0	0	0	0
0.032	0	0	0	0
0.058	0	4	5	5
0.1	6	10	10	10
0.18	10	10	10	10

Table 2: Symptoms observed at the different test concentrations

Conc. nominal mg/l	Swimming behaviour				Loss of equilibrium				Respiratory function				Exophtalmus				Pigmentation			
	24	48	72	96	24	48	72	96	24	48	72	96	24	48	72	96	24	48	72	96h
Blank	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Vehicle	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
0.01	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
0.018	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
0.032	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
0.058	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
0.1	1				1				0				0				0			
0.18																				

Effect : 0: normal  
 1: slight  
 2: moderate  
 3: severe

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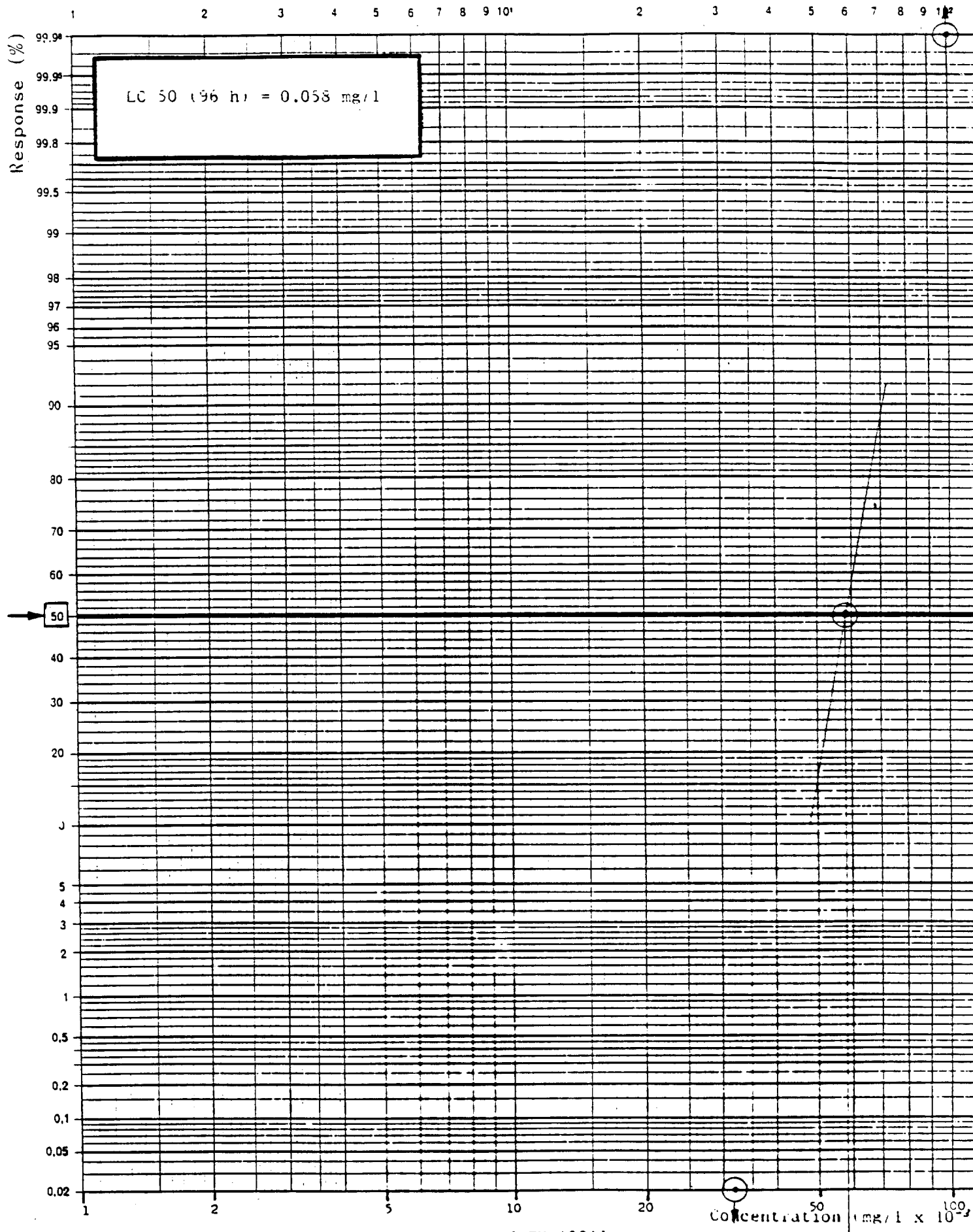


Fig. 1: Graphical determination LC 50 (96 h) of TK 10011

Project No.: 884049

TK 10011

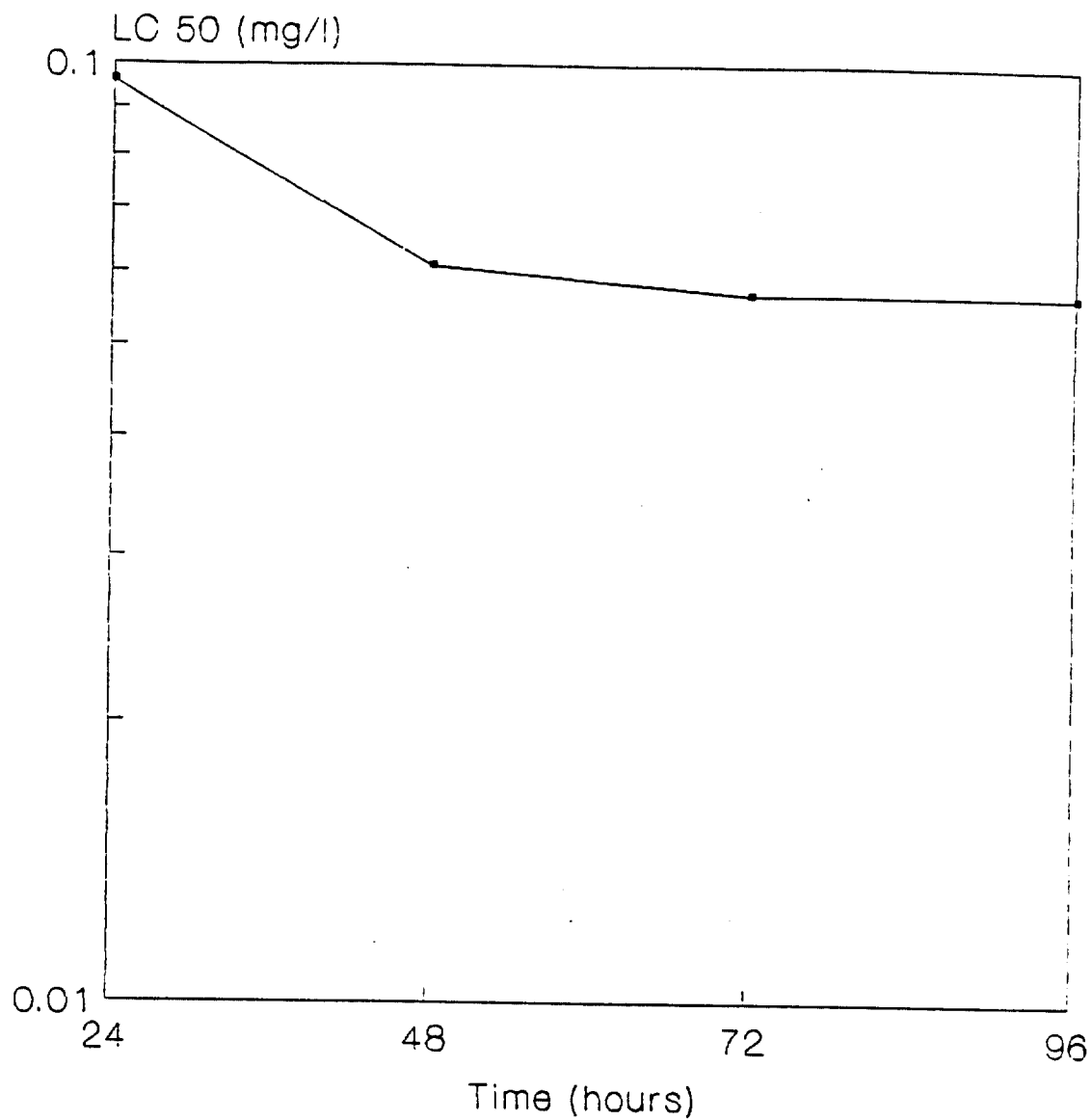


Fig. 2: Time/Toxicity Curve



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

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444 Saw Mill River Road  
Ardsley, New York 10502-2699

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

APR 24 1995

EPA acknowledges the receipt of information submitted by your organization under Section 8(e) of the Toxic Substances Control Act (TSCA). For your reference, copies of the first page(s) of your submission(s) are enclosed and display the TSCA §8(e) Document Control Number (e.g., 8EHQ-00-0000) assigned by EPA to your submission(s). Please cite the assigned 8(e) number when submitting follow-up or supplemental information and refer to the reverse side of this page for "EPA Information Requests".

All TSCA 8(e) submissions are placed in the public files unless confidentiality is claimed according to the procedures outlined in Part X of EPA's TSCA §8(e) policy statement (43 FR 11110, March 16, 1978). Confidential submissions received pursuant to the TSCA §8(e) Compliance Audit Program (CAP) should already contain information supporting confidentiality claims. This information is required and should be submitted if not done so previously. To substantiate claims, submit responses to the questions in the enclosure "Support Information for Confidentiality Claims". This same enclosure is used to support confidentiality claims for non-CAP submissions.

Please address any further correspondence with the Agency related to this TSCA 8(e) submission to:

Document Processing Center (7407)  
Attn: TSCA Section 8(e) Coordinator  
Office of Pollution Prevention and Toxics  
U.S. Environmental Protection Agency  
Washington, D.C. 20460-0001

EPA looks forward to continued cooperation with your organization in its ongoing efforts to evaluate and manage potential risks posed by chemicals to health and the environment.

Sincerely,

*Terry R. O'Bryan*  
Terry R. O'Bryan  
Risk Analysis Branch

Enclosure

13349A



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### Triage of 8(e) Submissions

Date sent to triage: 12/14/95

NON-CAP

CAP

Submission number: 13349A

TSCA Inventory:

Y

N

D

Study type (circle appropriate):

Group 1 - Dick Clements (1 copy total)

ECO

AQUATO

Group 2 - Ernie Falke (1 copy total)

ATOX

SBTOX

SEN

w/NEUR

Group 3 - Elizabeth Margosches (1 copy each)

STOX

CTOX

EPI

RTOX

GTOX

STOX/ONCO

CTOX/ONCO

IMMUNO

CYTO

NEUR

Other (FATE, EXPO, MET, etc.): \_\_\_\_\_

Notes:

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Contractor reviewer :

LPS

Date:

4/14/95

CECATS TRIAGE TRACKING DBASE ENTRY FORM

CECATS DATA: Submission # 8EHO 0395-13349 SEQ. A  
 TYPE: INT SUPP FLWP  
 SUBMITTER NAME: Ciba-Geigy Corporation

INFORMATION REQUESTED: FLWP DATE: \_\_\_\_\_  
 0501 NO INFO REQUESTED  
 0502 INFO REQUESTED (TECH)  
 0503 INFO REQUESTED (VOL ACTIONS)  
 0504 INFO REQUESTED (REPORTING RATIONALE)  
 DISPOSITION:  
0639 REFER TO CHEMICAL SCREENING  
0678 CAP NOTICE

VOLUNTARY ACTIONS:  
 0401 NO ACTION REPORTED  
 0402 STUDIES PLANNED IN FUTURE  
 0403 NOTIFICATION OF WORK IN PROGRESS  
0404 LABEL/MSDS CHANGES  
 0405 PROCESS/ANALYSIS CHANGES  
 0406 APP/USE DISCONTINUED  
 0407 PRODUCTION DISCONTINUED  
 0408 CONFIDENTIAL

SUB. DATE: 03/02/95 OTS DATE: 03/03/95 CSRAD DATE: 03/15/95

CHEMICAL NAME: \_\_\_\_\_  
 CAS# 71566-26-2  
81361-02-6  
none

Orasol Gelb 3R

INFORMATION TYPE:	P F C	INFORMATION TYPE:	P F C	INFORMATION TYPE:	P F C
0201 ONCO (HUMAN)	01 02 04	0216 EPICLIN	01 02 04	0241 IMMUNO (ANIMAL)	01 02 04
0202 ONCO (ANIMAL)	01 02 04	0217 HUMAN EXPOS (PROD CONTAM)	01 02 04	0242 IMMUNO (HUMAN)	01 02 04
0203 CELL TRANS (IN VITRO)	01 02 04	0218 HUMAN EXPOS (ACCIDENTAL)	01 02 04	0243 CHEM/PHYS PROP	01 02 04
0204 MUTA (IN VITRO)	01 02 04	0219 HUMAN EXPOS (MONITORING)	01 02 04	0244 CLASTO (IN VITRO)	01 02 04
0205 MUTA (IN VIVO)	01 02 04	0220 ECO/AQUA TOX	01 02 04	0245 CLASTO (ANIMAL)	01 02 04
0206 REPRO/TERATO (HUMAN)	01 02 04	0221 ENV. OCCURRENCE	01 02 04	0246 CLASTO (HUMAN)	01 02 04
0207 REPRO/TERATO (ANIMAL)	01 02 04	0222 EMER INCI OF ENV CONTAM	01 02 04	0247 DNA DAM/REPAIR	01 02 04
0208 NEURO (HUMAN)	01 02 04	0223 RESPONSE REQUEST DELAY	01 02 04	0248 PROD/USE/PROC	01 02 04
0209 NEURO (ANIMAL)	01 02 04	0224 PROD/COMP/CHEM ID	01 02 04	0251 MSDS	01 02 04
0210 ACUTE TOX. (HUMAN)	01 02 04	0225 REPORTING RATIONALE	01 02 04	0299 OTHER	01 02 04
0211 CHR. TOX. (HUMAN)	01 02 04	CONFIDENTIAL	01 02 04		
0212 ACUTE TOX. (ANIMAL)	01 02 04	ALLERG (HUMAN)	01 02 04		
0213 SUB ACUTE TOX (ANIMAL)	01 02 04	ALLERG (ANIMAL)	01 02 04		
0214 SUB CHRONIC TOX (ANIMAL)	01 02 04	METAB/PHARMACO (ANIMAL)	01 02 04		
0215 CHRONIC TOX (ANIMAL)	01 02 04	METAB/PHARMACO (HUMAN)	01 02 04		

TRIAGE DATA: NON-CBI INVENTORY YES  
 CAS SR NO  
 IN HUMAN NO  
 USE: Pigment  
 PRODUCTION: import  
 for organic solvent based ink products

03/15/95 Non-Cap